March 25, 2003

Dockets Management Branch (HFA –305)
Food and Drug Administration
5630 Fishers Lane, rm 1061
Rockville, MD USA 20852

Dear Sirs

Re: -02N-0276: registration 02-N-0278: Prior Notice

Comments on Seminar on Bioterrorism

1. Registration of Food Facilities

This will need to be done after October 12 and before December 12, 2003.

Concern:

That there will be such an influx of registration that the system will crash.

Suggestion:

Divide up the alphabet so that A-D has four days in which to register, E-H, four days, etc. If the time frame is divided into 4-working day increments – it may be more manageable.

2. Who Must Register?

- Foreign facilities must have an U.S. agent AND may choose to designate their U.S. agent as their agent-in-charge for purposes of registration.
- U.S. agent must *reside or maintain a place of business* in the United States

Concern:

1. Dealing directly with the manufacturer is surely the most efficient practice there could be. The responsibility for the goods is totally on the manufacturer, in who's interest it is to present only accurate information.

2. Cost factor for finding and hiring such a person.

3. Responsibility for delays created (and therefore costs involved*) if the inputting of any of the information is incorrect. A legal agreement will need to be set in place. Another cost.

4. Time lost in the translation of information from manufacturer to the agent and then to FDA.

Suggestion:

Deal directly with the manufacturer. A cleaner more direct relationship. The FDA is already requiring 24 hour contact numbers to deal directly with the manufacturer in case of trouble – so deal directly all the way through.

The manufacturer is already processing the required data. Allowing the manufacturer to issue its own notices will increase data accuracy, timeliness and keep costs lower.

I don't believe that having a US agent will reduce the threat of terror.

3. Proposal – Who is authorized to provide prior notice?

- The purchaser or importer of an article of food (or their agent) who resides or maintains a place of business in the U.S.
- The arriving carrier or in-bond carrier, if the article of food is imported for in-bond movement through the U.S. for export.

Concern & Suggestion

Stated under # 2.

4. What if the Information Changes after I submit a prior notice?

- Amendments – relates to *identity* of the product
- To allow submitter to provide specifics that did not exist by deadline for initial submission
- May be amended *once* if information did not exist at time of initial submission
- Initial prior notice submission must indicate "will amend"
- Cannot amend the *nature* of the food (e.g. Can't change fish to shrimp
- Due ≥ 2 hours before arrival at port of entry
- Updates – required if anticipated arrival is:
- 1 hour or more *earlier* than submitted; or
- 3 hours or more *later* than originally submitted
- Due ≥ 2 hours before arrival at port of entry
- All other changes – cancel initial prior notice and submit a new prior notice.

Concern:

1. LTL shipments. The manufacturer is often "at the mercy" of the trucking company in LTL – while the trucking company works to fill his truck to bring the freight costs down.

2. Having a window of 4 hours only getting to the border is unreasonable. It also puts an unreasonable responsibility on the trucking companies who are competing to keep the rates.

3. Retailers are also penalizing manufacturers if the product arrives late. If now, a trucking company fails to communicate that they cannot arrive within the four hour window required for the border – and another "prior notice" needs to be submitted, the product will definitely arrive late at the customer's warehouse - thus incurring penalties plus the costs of the trailer in "demurrage" has to be paid.

Suggestion:

1. The trucking company should be able to make the appointment with the border and refer to "tracking numbers" that are assigned with the "prior notice receipts".

2. Trucking companies all work with Pro-bill numbers and these can always be pre-assigned so therefore it could be included on the FDA notification documents which would then authorize the carrier to "update" the notification.

3. Increase the "window" of time to a reasonable period (taking into consideration Canada's inclement weather).

I respectfully submit my comments to the FDA.

Cordially

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